Supreme Court, U. S.
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80-482

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

LEAD INDUSTRIES ASSOCIATION, INC.,
Petitioner,

v.

ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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QUESTIONS PRESENTED

1. Whether, in light of the Court's decision in *Industrial Union Dep't* v. *American Petroleum Inst.*, 100 S.Ct. 2844 (1980) (the benzene case) and the provisions of the Clean Air Act, the Environmental Protection Agency (EPA) may establish a primary air quality standard designed to prevent the occurrence of human biological responses which have not been found to present a significant risk of harm to health.

2. Whether EPA may not only design a primary air quality standard to prevent the occurrence of biological responses not shown to present a significant risk of harm, but may incorporate in that standard multiple margins of safety that further remove the standard from legitimate health protection.

3. Whether EPA may establish a secondary air quality standard to protect the public welfare at the same level as a primary standard without making any independent findings to support the secondary standard.

LIST OF PARTIES TO THE PROCEEDINGS BELOW

Petitioners below were the Lead Industries Association, Inc. (LIA), a non-profit trade association whose 78 member companies include most U.S. producers and commercial consumers of lead, and St. Joe Minerals Corporation. EPA was the respondent. The Bunker Hill Company was an intervenor. The Natural Resources Defense Council, Inc., and the Air Resources Board of the State of California participated as *amici curiae.*

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OPINIONS BELOW

The opinion of the Court of Appeals, not yet officially reported, is reproduced in Appendix A. The regulation in question was published in 43 Fed. Reg. 46246-63, October 5, 1978, and is reproduced in Appendix B.

JURISDICTION

The judgment of the Court of Appeals was entered on June 27, 1980. This petition is being filed within 90 days of that date. The Court's jurisdiction is invoked under 28 U.S.C. §1254(1).

STATUTE AND REGULATIONS INVOLVED

Sections 108(a)(1) and (2) of the Clean Air Act, as amended, 42 U.S.C. §§7408(a)(1) and (2), require EPA's Administrator to publish a list of airborne pollutants which, in his judgment, "may reasonably be anticipated to endanger public health or welfare," and then to issue "air quality criteria" (more familiarly known as "Criteria Documents") reflecting "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." The statutory provisions in question in this case, Sections 109(b)(1) and (2) of the Act, 42 U.S.C. §§7409(b)(1) and (2), provide for adoption of national primary and secondary air quality standards for listed pollutants, as follows:

> "(1) National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.
>
> (2) Any national secondary ambient air quality standard prescribed under subsection (a) of this section shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated."

The regulation in question sets forth EPA's national ambient air quality standards for lead, 40 C.F.R. §50.12 (Appendix B).

STATEMENT OF THE CASE

This case, which concerns EPA's establishment of national primary (public health) and secondary (public welfare) ambient air quality standards for lead under the Clean Air Act, raises questions with respect to EPA's standard-setting powers that are of importance to all industries regulated by EPA and that have never before been considered by the Court.

In the regulatory proceedings below, EPA developed the primary lead standard by first determining what it considered the highest safe concentration of lead in the blood of children, the most sensitive segment of the population. The Agency then made a series of calculations to determine what limit on concentrations of lead in the air was necessary to assure that individual children's blood lead concentrations would not exceed the safe level.

A blood lead concentration of 40 micrograms per deciliter[1] has heretofore been considered to be safe for children. This is based on the premise that the threshold adverse health effect associated with lead exposure is anemia which occurs at blood lead concentrations well above 40 ug/dl. Consistent with that view, in its 1975 proceedings to reduce the lead content of gasoline EPA concluded that blood lead concentrations threaten the health of children at some level above 40 ug/dl, and established its lead-in-gasoline phasedown rules on the assumption that a blood lead level of 40 ug/dl was a safe upper limit for children, see *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 38-39 (D.C. Cir.) (*en banc*), *cert. denied*, 426 U.S. 941 (1976).

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[1] Concentrations of lead in blood, or blood lead levels, are expressed as micrograms of lead per deciliter of blood (ug/dl).

However, the Criteria Document published by EPA in December 1977, when it first proposed the lead standards at issue here, contained passages discussing a biological response known as erythrocyte protoporphyrin (EP) elevation that is associated with lead and is detectable at blood lead levels below 40 ug/dl.[2] The Criteria Document concluded that EP elevation is "relevant to human health" because it "indicates" impaired heme synthesis and mitochondrial function (42 Fed. Reg. 63078, December 14, 1977).[3]

When it published the lead Criteria Document, EPA simultaneously proposed a national primary air quality standard limiting airborne concentrations of lead to 1.5 micrograms of lead per cubic meter of air (ug/m^3) because of the Agency's concern over the health implications of EP elevation (42 Fed. Reg. 63075, 63078). In doing so, EPA acknowledged that there was "scientific controversy" about "the health significance of abnormal biological effects associated with blood lead levels below traditional levels of concern" (42 Fed. Reg. 63077). EPA simultaneously proposed a national secondary air quality standard at the same level as the primary standard

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[2] A biological response or effect is a deviation from the norm that is usually detectable only by special laboratory tests. The body constantly experiences many such deviations with no adverse impact on health.

[3] The reference to heme synthesis impairment means that lead affects certain chemical steps in the production of heme, a constituent of hemoglobin, the oxygen-carrying component of the body's red blood cells. This does not, however, mean that the production of heme or hemoglobin is reduced, or that the body is in any way injured. Mitochondria are part of the body's cells and play an important role in cell respiration. What the Criteria Document meant by impairment of mitochondrial function is unclear, but there was no suggestion in the Criteria Document that cell respiration is affected in any way at blood lead levels below 40 ug/dl.

stating only that it could find no grounds for a secondary standard more stringent than the primary one (42 Fed. Reg. 63081-82).

Because of the admitted scientific controversy over the health significance of the biological responses that occur at low blood lead levels, EPA sought public comment "on whether what is known, or anticipated, about EP elevations or other subclinical effects has sufficient implications to warrant a role in determining the level of the standard" (42 Fed. Reg. 63079). EPA further noted that it "could take the position that EP elevation, while of concern to public health, is not sufficiently adverse to health, and that the standard should be based on the more severe effects such as anemia, or CNS [central nervous system] deficits" (*id.*).

A hearing was held at which only three medical witnesses testified in support of the proposed standard, while a number of medical authorities in the fields of hematology and pediatric lead health effects testified or filed statements challenging the scientific and medical bases of the standard.[4] The witnesses in opposition stated that elevated EP is not harmful but instead serves as an indicator of biological change or response, that heme synthesis is not impaired unless the production of

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[4] The latter witnesses included Dr. J. Julian Chisolm, Jr., Senior Staff Pediatrician, Baltimore City Hospital and Associate Professor of Pediatrics, Johns Hopkins University School of Medicine, and a consultant to EPA's Science Advisory Board; Dr. James Jandl, Minot Professor of Medicine, Harvard Medical School; Dr. Edward McCabe, Assistant Professor of Pediatrics, University of Wisconsin Medical School; Dr. Henrietta K. Sachs, a pediatrician and former director of the Chicago Lead Clinic; and Drs. James McNeil and Ronald Panke, practicing physicians who had conducted studies of the effects of lead on children living near lead smelters.

heme is in fact reduced, and that no studies had shown reduced hemoglobin at blood lead levels below 40 ug/dl.

Testimony and comments were also submitted demonstrating that the proposed primary standard not only was designed to prevent the occurrence of biological responses that had not been shown to be harmful, but was further removed from legitimate health protection by the incorporation of multiple and cumulative safety margins. An example of such a margin is the fact that, though the Criteria Document states that lead sulfide is virtually insoluble (and, it follows, is unlikely to be absorbed in children's blood to any appreciable extent) and that children are unlikely to inhale particles above a certain size, lead sulfide and large lead particles were not excluded from the standard. Another example is the fact that at numerous points in the arithmetical process used to determine the maximum air lead level required to maintain children's blood lead levels below 30 ug/dl, EPA took an excessively conservative approach, thereby adding a series of safety factors that had the effect of cumulating and compounding the safety margin.

LIA also submitted evidence showing that the 1.5 ug/m^3 standard was impossible to attain and would result in a virtual shutdown of U.S. lead production by forcing the closure of 45 primary and secondary lead smelters representing over 80 percent of total U.S. lead production capacity.[5]

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[5] This point was never disputed by EPA, and upon promulgation of the final lead standard EPA's Administrator acknowledged that "some nonferrous smelters may not be able to technically or economically achieve the standard," 9 ENVIR. REP. (BNA) 1091 (Current Developments, October 6, 1978).

Nonetheless, in October 1978 EPA adopted final air lead standards at the same level it had proposed, 1.5 ug/m^3. The primary standard was designed to maintain children's blood lead levels below 30 ug/dl, though the Agency failed to find any significant risk of harm at this level. While EPA found that blood lead levels below 20 ug/dl presented no "significant risk" and that those above 40 ug/dl were "clearly adverse" (App. 143a), it made no clear-cut findings concerning the health significance of a 30 ug/dl blood lead level.[6] Thus, at one point in the preamble to the final regulation EPA said that it did not have "sufficient information" to rule out the possibility of harm at blood lead levels below 40 ug/dl (App. 127a). At another point EPA stated that impaired heme synthesis is "potentially adverse" to health at blood lead levels of 30 ug/dl (App. 143a), while elsewhere in the preamble EPA found that heme synthesis is not impaired until blood lead levels exceed 40 ug/dl (App. 153a), and in still another place EPA found only that impaired heme synthesis is "not without health significance" and that EPA has "concern" about its effects at blood lead levels above 30 ug/dl (App. 135a, 150)a. At no point did EPA find that blood lead levels between 30 and 40 ug/dl present a significant risk of harm to health.

In addition to showing uncertainty as to the medical significance of blood lead levels between 30 and 40 ug/dl, EPA did not define what it meant by "adverse to health." Most importantly, EPA did not find that heme

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[6] Using EPA's formula for calculating the lead standard, establishment of 40 ug/dl, rather than 30 ug/dl, as the maximum safe blood lead level would have resulted in a standard of about 4 ug/m^3, one which would have caused much less harm to the lead industry than the 1.5 ug/m^3 standard EPA adopted.

synthesis impairment at blood lead levels below 40 ug/dl causes illness, reduces a child's functional or learning capacity, results in shortened life span, leads to higher susceptibility to disease, or causes any other manifestation of health impairment. As an apparent fallback position, EPA said that it was adopting 30 ug/dl as the maximum safe blood lead level in order to protect against anemia (App. 128a), yet EPA in fact found that anemia does not occur until blood lead levels reach 40 ug/dl, and even then EPA found only that "symptoms" of anemia "may" occur at that level (*id.*).[7]

Following the promulgation of the final lead standards, LIA petitioned EPA to reconsider and stay the regulations and petitioned for judicial review in the District of Columbia Circuit pursuant to Section 307(b) of the Act, 42 U.S.C. §7607(b). EPA denied the petition in February 1979, and the court below affirmed the rules in its opinion which is the subject of this petition for certiorari.

The opinion of the court below, which was issued before this Court's decision in *Industrial Union Dep't* v. *API,* did not focus on EPA's duty to set standards on the basis of significant risks of harm to health, but held that Section 109 authorizes EPA to establish primary air quality standards without showing "that there is a medical consensus that the effects on which [such standards are] based are '*clearly harmful to health*' " (App. 47a). Instead, under the court's holding, all that the

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[7] The Criteria Document does not state that anemia has been found to occur at a blood lead level of 40 ug/dl, and there was abundant evidence that it occurs above that level (App. 56a n. 67, 143a).

statute requires "is evidence in the record which substantiates [EPA's] conclusions about the health effects on which the standards were based" (*id.*).

The court also affirmed EPA's use of multiple margins of safety in setting the standards, ruling that under Section 109(b), which authorizes a "margin of safety," EPA's approach constituted "a policy choice of the type that Congress specifically left to the Administrator's judgment," and the court "must allow him the discretion to determine which approach will best fulfill the goals of the Act" (App. 61a-62a).

In addition, the court ruled that EPA's setting the secondary standard at the same level as the primary standard, without supporting findings showing that the secondary standard is necessary to protect the public welfare, was not improper because this "imposed no additional burdens on the industry" (App. 103a).

The court also rejected several other challenges by the industry petitioners, and EPA's 1.5 ug/m^3 primary and secondary lead standards were affirmed.

ARGUMENT

The Court should exercise its discretionary jurisdiction to review the decision of the Court of Appeals in this case. The opinion below authorizes EPA to adopt health standards without finding that such standards are reasonably necessary to eliminate significant risk of harm to health and thus conflicts with the Court's decision in *Industrial Union Dep't* v. *API,* 100 S.Ct. 2844 (1980), and the provisions of the Clean Air Act. The decision of the court below that EPA may use multiple and compounded margins of safety, and may adopt a standard to protect the public welfare without making independent

findings in support of the standard, likewise conflicts with the Clean Air Act and presents important issues of Federal law that should be finally resolved by the Court.

I. The Decision Below Is In Conflict With The Court's Recent Decision In *Industrial Union Dep't* v. *API.*

The plurality opinion in the benzene case held that the Occupational Safety and Health Administration may adopt a health standard limiting the concentrations of a pollutant in workplace air only when such a standard is supported by findings demonstrating that the standard is "reasonably necessary" to prevent a "significant risk" of "harm" or "material health impairment" from a "proven hazard," *Industrial Union Dep't* v. *API,* 100 S.Ct. 2855, 2863, 2869. Moreover, the plurality opinion states that the agency must show that its findings as to what constitutes harm to health are supported by "a body of reputable scientific thought," *id.* at 2871. OSHA's benzene standard, which established a 1 ppm maximum concentration limit, was overturned because OSHA failed to show that workers are exposed to "significant risk" of "material harm" at benzene air concentrations below 10 ppm, but had developed only "sketchy evidence" on that subject, *id.* at 2859.

While the language of the Clean Air Act governing the establishment of air quality health standards is different from that of the Occupational Safety and Health Act, the thrust and purpose of the two laws are identical insofar as health protection is concerned. Both acts direct the respective agencies to set standards only on the

basis of "significant" risk of material health harm.[8] Further, as we will show below, the legislative history of the Clean Air Act makes it clear that the requirement of the Act that national primary ambient air quality standards shall be "requisite to protect the public health" means that such standards must be designed to prevent effects that are clearly adverse to health (*infra,* pp. 14-17). Indeed, Congress explicitly recognized that attempts to develop standards that would eliminate all health effects, not merely those that are clearly harmful, would cause unacceptable damage to the Nation's economy, and Congress warned EPA against adopting "no effects" standards (*infra,* p. 15).

Hence, there is no substantive difference between the requirement imposed on OSHA that standards be "reasonably necessary" to prevent "significant risk" of "material health impairment" and the requirement that EPA's standards be designed to prevent effects that are adverse to health. In both instances, Congress intended the agencies to restrict their standard-setting activities to the prevention of real harm. And there is no reason why the plurality's requirement that OSHA's medical judgments be supported by a "body of reputable scientific thought" would apply any less to EPA's judgments.

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[8] The legislative history of the Clean Air Act expressly endorses the "significant risk" approach. In *Ethyl Corp.* v. *EPA,* 541 F.2d at 13, the court held that EPA must regulate on the basis of a "significant risk of harm." In enacting the 1977 Amendments to the Clean Air Act, Congress specifically adopted this position and applied it to all sections of the Act concerning public health protection. See H.R. REP. No. 95-294, 95th CONG., 1st SESS. 43-49 (1977). In setting the lead standard, EPA itself has spoken in terms of "significant risk." See p. 7, *supra.*

In sum, the following principle expressed by the Chief Justice in his concurring opinion in the benzene case applies with equal force to EPA's lead standard:

> "When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation. Perfect safety is a chimera; regulation must not strangle human activity in the search for the impossible" (100 S.Ct. at 2875).

It is readily apparent, following the reasoning of the benzene case, that EPA's lead standard suffers from the same defect as OSHA's benzene standard — in neither case did the agency find, or was it able to show, that its health standard was required to prevent a *significant* risk of harm. In EPA's case, the Agency was simply unable ultimately to find or to demonstrate that blood lead levels between 30 and 40 ug/dl present a significant risk of harm. All that EPA was ever able to find was that lead affects a bodily function at 30 ug/dl, and that this was grounds for "concern" (App. 127a, 150a).

Thus, although EPA determined that EP elevation and associated impaired heme synthesis may occur at blood lead levels as low as 30 ug/dl, it never explained how these phenomena are harmful at levels below 40 ug/dl. While EPA found that blood lead levels below 20 ug/dl presented "no significant risk" and that those above 40 ug/dl were "clearly adverse" (App. 143a), it was never able to conclude that a significant risk of harm exists at levels between 30 and 40 ug/dl, confining itself to statements that blood lead levels within this range present "some degree" of health risk or are "not without health significance" (42 Fed. Reg. 63079, App. 135a).

Such an approach to establishing national environmental standards is clearly prohibited by the benzene plurality opinion. Moreover, EPA was no more able to point to "a body of reputable scientific thought" supporting its conclusion that 30 ug/dl is the maximum safe blood lead level than was OSHA in concluding that benzene presents a cancer hazard at exposure levels below 10 ppm.[9]

In its search of the record, the court below was as unsuccessful as EPA was in pinpointing adverse health effects at blood lead levels of 30 ug/dl. The court was able to state only that EP elevation "indicates" that lead has begun to "affect" biological functions in the body; that it is an "indication" of an impairment which "affects" human health; that it "indicates" an impairment of the mitochondria and that lead has begun to "affect" heme synthesis; that it "may indicate" a reduction in reserve capacity; and that impairment of heme synthesis "suggests" that lead "may" also interfere with other heme proteins (App. 52a).[10]

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[9] Of the three medical witnesses who supported EPA's proposed lead standard at the Agency's hearing, two appear to take the view that lead should be eliminated from the environment entirely because it is not beneficial to humans and is harmful at high blood lead levels, an approach akin to OSHA's carcinogen policy which branded benzene dangerous at any exposure level because it was implicated as a carcinogen at high exposure levels (App. 123a, 167a, 169a).

[10] The court attempted to bolster this discussion by citing an earlier section of its opinion (App. 51a n. 57), but there the court was addressing "severe neurological effects of high lead exposure" which occur at 80-100 ug/dl in children and at 100-200 ug/dl in adults, and "impaired neural and cognitive functions" which appear to start for some children at a range of 50-60 ug/dl (App. 13a-14a). In short, neither EPA nor the court below succeeded in explaining how blood lead levels below 40 ug/dl adversely affect the public health.

The Court of Appeals' affirmance of EPA's regulation thus has the practical effect of leaving EPA free to adopt whatever health standards it wishes merely by finding that the pollutant in question affects a bodily function or causes some deviation from an ideal state whether or not a significant health risk is present. Congress no more intended such a broad grant of authority to EPA than it did to OSHA, and this petition should be granted so as to make clear the bounds of EPA's standard-setting authority.

II. This Case Presents Questions Of Exceptional Importance Under The Clean Air Act That Should Be Decided By The Court.

Quite apart from the conflict with the plurality's opinion in *Industrial Union Dep't* v. *API,* EPA's approach to standard-setting in the lead case is at odds with the Clean Air Act, and grant of this petition is necessary to prevent EPA from persisting in similar efforts to impose standards that are both crippling to industry and unnecessary to protect the public health.

A. Primary standards may not be designed to prevent biological responses not shown to be adverse or to present a significant risk of harm to health.

Primary ambient air quality standards are not goals but enforceable requirements that must be met within prescribed deadlines pursuant to state implementation plans under Section 110, 42 U.S.C. §7410. As we have pointed out earlier, the possibility that excessively severe primary standards could cause serious economic dislocation was not lost on Congress, and the legislative history of the Clean Air Act makes it clear that EPA's authority

under Section 109(b) is limited to the establishment of standards to protect the public from effects that are clearly adverse to health. That same history also shows that Congress did not intend to authorize EPA to adopt primary standards which would force the virtual closure of an important United States industry in order to prevent biological responses without showing how those responses are harmful.

The Senate Report on the 1970 amendments to the Clean Air Act, which established the present standard-setting scheme of Section 109, stated that EPA "would be required to set a national minimum standard of air quality," S. REP. No. 91-1196, 91st CONG., 2d SESS. 10 (1970). Senator Muskie, the Act's chief sponsor in the Senate, later explained that the concept of "minimum standards" meant that there were limits as to what the standards could be expected to accomplish in the way of health protection:

> "With respect to the national primary and secondary air quality standards, those are not clean air standards. Those are minimal standards. We made them minimal in order to achieve a realistic goal for cleanup in dirty air areas, so they are minimal. . . . They were written as the minimal burden we could impose upon the dirty air areas of the country to clean up without bringing their economies to a screeching halt." *Hearings on S. 251, S. 252 and S. 253 Before Subcomm. on Environmental Pollution of Senate Comm. on Environment and Public Works,* 95th Cong., 1st Sess., Part 3 at 37 (1977).

The approach outlined by Senator Muskie is echoed in other statements in the Act's legislative history that "no effects" thresholds are not only impossible to achieve, but are impractical and unwise from an economic and social standpoint. See, *e.g.*, H.R. REP. No. 95-294, *supra*, at 127. The fact that Congress did

not contemplate that the primary standards would lead to serious economic dislocation, and that primary standards were never expected to eliminate all health "effects" but only those that are clearly adverse, is further emphasized in the following statement by Senator Muskie during the debate on the 1977 amendments to the Act:

> "[T]he national primary and secondary standards were set for dirty air areas as the minimum necessary and the minimum reasonably attainable in the dirty air areas, in order to put them up to minimal health standards. They are not ultimate; they are not maximum; they are minimal. * * * *Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.*" 123 CONG. REC. S 9423 (daily ed. June 10, 1977) (emphasis added).

The very language of Section 109 reflects the concern expressed by Congress that primary standards not be imposed in a fashion that seeks to achieve a "no effects" level at any cost. Unlike the primary standards which must be met within tight deadlines, the secondary or welfare-based standards must be met within a "reasonable" time, and issues of technological and economic feasibility enter into state implementation plan timetables for meeting secondary standards. For that reason, Congress established the extremely broad-reaching requirement that secondary standards "must be requisite to protect the public welfare from any known or anticipated adverse effects," Section 109(b)(2), 42 U.S.C. §7409(b)(2). By contrast, Congress specified in the case of the primary standards only that they be "requisite to protect the public health," Section 109(b)(1), 42 U.S.C. §7409(b)(1), and according to the Senate Report to the 1970 legislation, "requisite to protect the public

health" means requisite to protect against "adverse effects," S. REP. No. 91-1196, *supra,* at 10.

The court below rejected the foregoing interpretation of the Act, stating that the Act was intended to be precautionary and standards may be designed to protect against "effects that have not yet been uncovered by research" (App. 45a). While the thrust of the Act is unquestionably precautionary, there is no way to avoid the fact that the legislative history passages quoted above show that Congress wanted precaution taken only against significant risks of harm, not unknown risks of possible harm. Moreover, the interpretation of the court below gives EPA's Administrator no guidance as to the limits of his standard-setting authority and leaves him free to interpret the statutory requirement that primary standards be "requisite to protect the public health" any way he wishes. The ruling of the court below is in conflict with the Clean Air Act and would sanction precisely the kind of standardless delegation that Mr. Justice Rehnquist found objectionable in his concurring opinion in the benzene case, 100 S.Ct. at 2878-87. For these reasons, and because these questions concerning EPA's standard-setting powers have such far-reaching consequences for American industry, the decision below should be reviewed by the Court.

B. EPA exceeded its authority by adopting multiple margins of safety.

While EPA's decision to adopt an air lead standard designed to maintain children's blood leads below 30 ug/dl would in and of itself have resulted in an excessively stringent standard, the stringency of the standard was greatly aggravated by the fact that EPA built in multiple and compounded margins of safety when it calculated the standard.

Thus, safety margins were applied not only in EPA's determination of the maximum safe blood lead level for children, but in its selection of an air lead/blood lead ratio of one unit in the air equals two units in the blood (App. 133a), as well as its estimate of the amount of blood lead attributable to non-air sources (App. 134a). Including non-respirable particles and those that are virtually insoluble in the primary standard (App. 137a) adds still another "margin of safety" since doing so has the effect of applying the standard to particles which cannot be deposited in the respiratory system or absorbed in the blood and thereby overestimates the contribution to blood lead from air sources (see *infra,* p. 6).

The point concerning the inclusion of large and virtually insoluble particles deserves emphasis. EPA conceded in the preamble to the final regulation that "some lead particles are too small or too large to be deposited in the respiratory system" (App. 137a). As noted earlier, the Criteria Document also observes that lead sulfide is virtually insoluble and absorption of lead sulfide through the lungs may be slight (App. 73a n.105). EPA never focussed on the question of solubility, and rejected LIA's contentions concerning particle size by saying that large particles "may, at some point, become respirable through weathering" (App. 137a). The court below sustained EPA's position in view of "the paucity of the information" on the subject of solubility and particle size (App. 73a). The fact remains that there was sufficient information for the drafters of the Criteria Document to make specific findings on these subjects and, as the plurality opinion in the benzene case points out, the burden is on the agency proposing a standard to develop the information needed to support its position, 100 S.Ct. 2870.

The importance of EPA's multiple safety margins to the level of the final standard cannot be overemphasized. Given the methodology EPA used in calculating the primary standard, relatively minor changes in such factors as the one employed to determine the impact of air lead exposure on blood lead levels (the so-called air lead/blood lead ratio) result in very significant changes in the standard. For example, had EPA chosen the air lead/blood lead ratio recommended in the first draft of the Criteria Document, rather than the ratio it ultimately employed, the final standard would have been 3 ug/m^3, twice as high as the standard it adopted, even assuming no change in the 30 ug/dl blood lead threshold.

Section 109(b)(1) of the Act, 42 U.S.C. §7409(b)(1), requires EPA to adopt primary air standards requisite to protect the public health "allowing an adequate margin of safety." Although the 1970 Senate Report said that a margin of safety should afford only a "reasonable degree of protection," S. REP. No. 91-1196, *supra,* at 10, and an "adequate" margin of safety has been held to embrace something less than an "ample" margin of safety, *Environmental Defense Fund* v. *EPA,* 598 F.2d 62, 81 (D.C. Cir. 1978), the court below nonetheless approved EPA's use of multiple and compounded margins of safety in setting the lead standard as a proper "policy choice" (App. 61a).

To say that Congress left EPA free to build in multiple and compounded margins of safety at each point in the analysis can only result in a final standard far more stringent than is necessary or achievable. Accordingly, the Court should review this issue, as the decision of the court below granting EPA unfettered discretion to construct margins of safety makes meaningless Section 109's directive that standards be limited to protecting the public health.

C. EPA must make independent findings to support secondary standards even though they are set at the same level as primary standards.

In establishing the secondary, or welfare-based, standard for lead at the same level as the primary, or health-based, standard, EPA merely said that there was no evidence that a secondary standard more restrictive than the primary one would be justified (App. 156a). This in turn was based on the conclusion that "animals do not appear to be more susceptible to adverse effects from lead than man, nor do adverse effects in animals occur at lower levels of exposure than comparable effects in humans" (*id.*). The court below affirmed the establishment of a secondary standard on this basis because, in its view, no additional burdens on industry were imposed (App. 103a). However, the court below was unable to cite the Clean Air Act, EPA's regulations or any judicial decisions in support of its holding.

In any event, if as we have urged the primary standard is invalid, the secondary standard must fall as well, for EPA made no findings that would independently support the secondary standard. Thus, EPA made no attempt to establish a rational connection between information in the Criteria Document on the effects of lead on plants, animals, climate, visibility, economic values, and other "welfare" considerations listed in Section 302(h), 42 U.S.C. §7602(h), and the adoption of a 1.5 ug/m^3 secondary standard. See *Kennecott Copper Corp.* v. *EPA,* 462 F.2d 846, 850 (D.C. Cir. 1972), where the secondary standard for sulfur oxides was remanded because EPA's Administrator had failed "to enlighten the court as to the basis on which he reached the [secondary] standard from the material in the Criteria." Accordingly, this issue also merits review by the Court.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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